GUIDANCE TO NOTIFIERS ON USE OF THE LOCAL LYMPH NODE ASSAY (08/05/02).

The UK c.a. will now accept the Local Lymph Node Assay (LLNA), conducted in the mouse, as a stand-alone test for skin sensitisation as part of a notification under the Notification of New Substances Regulations, 1993 (NONS). Negative results in the LLNA no longer require further confirmation by testing for skin sensitisation in the guinea pig. The protocol for conducting the LLNA is available in a new OECD guideline (no. 429).

The LLNA provides certain advantages with regard to animal welfare (most particularly refinement but also reduction) and also scientific aspects (such as the objective and quantitative nature of the end-point measured). The LLNA can also provide some information on the relative potency of contact sensitisers, unlike other methods currently available for skin sensitisation.

Given these significant advantages, the UK c.a. now considers that for notification purposes the LLNA is the method of first choice for skin sensitisation. Thus for new NONS skin sensitisation tests conducted from 1st October 2002, the use of alternative tests for skin sensitisation, such as those using guinea pigs, will require full justification on a case-by-case basis.

When submitting future notifications, the UK c.a. requests that notifiers summarise data from LLNA studies in section 4.7.0 'Additional toxicology tests' of the SNIF, and not in section 4.1.70 'Skin sensitisation'.

The following information should be provided in the section 4.7.0 summary:

End point investigated: Skin sensitisation
Description of the essential features of the test method: Local lymph node assay. Provide details of the vehicle, species/strain, sex and numbers of animals per group.
Results: State whether 'Positive' or 'Negative'. Provide stimulation index (SI) for each concentration tested (stimulation index = test DPM/control DPM) e.g. % SI 5 x 10 x 20 x
Test procedure used: OECD Guideline 429
Body responsible for test: Test house
Comments: Provide details of positive control used (e.g. identity, concentration, stimulation index)

For any comments or questions on this guidance note please contact:

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